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PROVISIONAL APPLICATION COVER SHEET [37 CFR 1.53(c)]

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Date : March 24, 2003
Docket No. : 49784/THD/A599
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Mail to: BOX PROVISIONAL PATENT APPLICATION

INVENTOR(S)/APPLICANT(S) (LAST NAME, FIRST NAME, MIDDLE INITIAL, RESIDENCE (CITY AND EITHER STATE OR FOREIGN COUNTRY)

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_____ Additional inventors are being named on separately numbered sheets attached hereto.

TITLE OF THE INVENTION (280 characters max)

BELOW ELBOW DYNAMIC SUPINATED SPLINT

APPLICANT(S) STATUS UNDER 37 CFR § 1.27

_X_ Applicant(s) and any others associated with it/them under § 1.27(a) are a SMALL ENTITY

ENCLOSED APPLICATION PARTS

_39_ Specification (number of pages)
_____ Drawings (number of sheets)
_____ Assignment
_____ Other (specify):
_X_ A check for the filing fee of $ 80.00 is enclosed.
The Commissioner is hereby authorized to charge any fees under 37 CFR 1.16 and 1.17 which may be required by this filing to Deposit Account No. 03-1728. Please show our docket number with any charge or credit to our Deposit Account. **A copy of this letter is enclosed.**

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

_X_ No ____ Yes, the name of the U.S. Government agency and the Government contract number are:

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PROVISIONAL APPLICATION FILING ONLY

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23363
PATENT TRADEMARK OFFICE

PATENT

PROVISIONAL APPLICATION

of

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For

UNITED STATES LETTERS PATENT

on

BELOW ELBOW DYNAMIC SUPINATION SPLINT

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A Supination Splint Worn Distal to the Elbow: A Radiologic, Electromyographic, and Retrospective Report

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Introduction:

Forearm rotation is necessary for various daily activities, such as feeding, dressing, and personal hygiene. It is also an integral component of motion for many vocations and avocations. Normal forearm rotation is approximately 0^0 to 80^0 or 90^0 for both supination and pronation.[1] A functional arc of forearm rotation is 100^0 (50^0 of supination and 50^0 of pronation).[2,3] While the loss of pronation can be compensated for by shoulder abduction[4], no degree of shoulder or elbow compensation can restore function when there is a significant loss of forearm supination.[5]

Forearm supination is dependent upon the complex interplay between the distal radioulnar joint (DRUJ), interosseous membrane, and the proximal radioulnar joint (PRUJ). Injuries or pathologies affecting any of these areas can potentially lead to loss of forearm supination (and/or pronation). Common conditions include: distal radius fractures, radial head fractures, Galeazzi and Monteggia fractures, Essex-Lopresti injury and any surgical procedures which change any of the structures listed above.[6]

Various dynamic splints have been designed to assist in increasing supination. The first dynamic forearm rotation splint was described by Bunnell in 1944.[7] As described by Bunnell[8], the elbow is fixed at 90^0, the wrist and hand are splinted in neutral, rubber bands are attached from a forearm piece to the radial and ulnar sides of the hand/wrist piece to create rotation. Although this early splint is no longer formally used, it has served as a template for more current forearm rotation splints.

Presently, two of the more frequently used dynamic forearm rotation splints, both of which cross the flexion/extension joints of the elbow, are the Colello-Abraham dynamic pronation/supination splint[9,10] and a commercially available dynamic supination/pronation kit (Smith and Nephew Rolyan, Inc., Germantown, WI) (Figure 1).[10,11] The Collelo-Abraham splint

consists of a humeral cuff, two lateral bars running parallel to the forearm, and a cock-up splint with multiple rings, to which rubber bands are attached from the lateral bars to provide the rotational force. One of the advantages of the Colello-Abraham splint is that the use of multiple force arms increases the area of force application and thus, decreases pressure and improves comfort.[12] The commercial splint kit employs a twisted rubber tube to generate the rotational force. One of the advantages of this splint is that it may be more time efficient, as construction of an outrigger is not required.[3]

The major problem with the dynamic forearm rotation splints used to date is that the elbow is fixed at 90^0. This elbow flexed position optimizes the attachment site for the proximal components of the aforementioned splints. The lack of elbow motion with currently available splints can limit the patient's functional use (i.e. eating, drinking, grooming, etc) of the splinted extremity, as the elbow is fixed at a 90^0 angle and does not permit any flexion or extension.

The splint described in this paper dynamically supinates the forearm but does not cross the elbow flexion and extension joints and hence, does not fix the elbow in flexion; thereby allowing the wearer adequate flexion and extension of the elbow for activities of daily living (ADLs). As well, the dynamic component of the splint allows the patient to temporarily rotate the forearm from supination to pronation to perform ADLs as necessary. Clinically, it is apparent that if function can be maintained it is more likely the patient will wear the splint for longer periods of time. In addition, the splint described here is less time consuming to construct than the three-part construction of the Colello-Abraham splint and it is less costly to produce than the commercial dynamic forearm rotation kits.

Purpose:

The purpose of this study is threefold: 1) To describe a new dynamic supination splint that approaches the humeroulnar and humeroradial flexion/extension joints of the elbow and is flared to allow flexion and extension, 2) provide retrospective data on the effectiveness of this splint in overcoming passive supination limitations in various patient populations and 3) provide radiographic images and electromyographic (EMG) data that documents the ability of this splint to provide a passive supination force.

Methods:

Eleven patients (2 males and 9 females) from 1998-2000 with various elbow and wrist fractures which led to a loss of forearm supination were assessed in this retrospective review (Table 1). Patient ages ranged from 38-70 years, with an average of 48.3 years (Table 2). All patients were right hand dominant with almost an equal distribution of injuries to the dominant or non-dominant extremity. Patients were seen for treatment ranging from 5 to 26 visits, with an average of 17.7 visits, over an average of 10.0 weeks (Table 3). The dynamic supination splint was, on average, issued on the fifth visit (range: 1-13 visits).

All subjects were treated by either the primary author (MJL) or senior author (AEV). All treatments which addressed loss of forearm supination were identical for all subjects both before and after splint application. Treatments consisted of: passive range of motion (PROM), active-assistive range of motion (AAROM), active range of motion (AROM), soft tissue mobilization to the pronators, resistive forearm rotation exercises, and moist heat while placed in a supination stretch utilizing a weight. The decision to splint was made either due to: 1) inadequate range of motion (ROM) gains or 2) per physician request due to limited ROM. An inadequate ROM gain was defined as the point when improvements in supination ROM became recalcitrant to the above treatment techniques. Subjects were instructed to wear the dynamic supination splint at

least 4 total hours per day, progressing to a maximum of 8 total hours. Duration of wearing time per wearing session and the number of times the splint was worn per day was determined by patient tolerance, with the total daily hours within the 4-8 hour limit.

Range of Motion Analysis

Goniometric measurements for PROM (Table 4) and AROM (Table 5) were taken after preconditioning[13], i.e. the restricting soft tissues had achieved their maximum length (without causing damage) via cyclic loading. Goniometric measurements were taken as described by Norkin and White[1]: the subjects were positioned in sitting with the shoulder in 0^0 of flexion, extension, abduction, adduction, and rotation so that the upper arm was next to the side of the body. The elbow was then flexed to 90^0 and the center of the goniometer was positioned lateral to the ulnar styloid process. One arm of the goniometer was aligned with the anterior mid-line of the humerus and the other was placed across the volar aspect of the forearm, just proximal to the styloid processes.

A repeated measures analysis of variance (ANOVA) was utilized to determine statistical significance between subjects and between phases of rehabilitation. Phases of rehabilitation were defined as: initial, middle, and discharge. As measurements were not originally taken at specific intervals, the middle phase of rehabilitation value was determined as the closest measurement to the total number of visits divided by two. A post-hoc Tukey multiple pairwise comparison test was also utilized to isolate differences between each phase of rehabilitation.

Radiographic Analysis

For the radiographic analysis, one female subject (age: 26), who was not a subject in the retrospective review as she had no previous history of injury or ROM limitations, was positioned for a standard wrist variance film (Figure 2).[8] The shoulder was abducted to 90^0, the elbow was

flexed to 90^0, and the film was then taken posterior to anterior. Three films in the wrist variance position were taken for analysis: resting position without the splint, maximal active forearm supination without the splint, and passive position of the forearm in supination while wearing the splint. An additional radiograph was taken with the shoulder abducted to 90^0, elbow fully extended, and humerus internally rotated. The forearm was passively supinated by the splint and the radiograph was taken posterior to anterior as with the wrist variance view. No statistical analysis was used to assess the radiographic positions, rather the reader is encouraged to review the film images provided (Figure 5).

Electromyographic Analysis

The EMG analysis was performed using the same subject as the radiographic analysis (at a different date). Bipolar surface, silver chloride electrodes, with an inter-electrode spacing of 2 cm and a detector surface diameter of 1 cm, were utilized. One electrode was placed over the supinator muscle and a second was placed over the bicep (Figure 3). A common ground was placed over the ipsilateral scapula. Multiple trials were performed to differentiate wrist extensor versus supinator muscle activity to determine optimal electrode placement. EMG analysis was used to study three conditions: 1) resting, quiescent muscle position, 2) maximal isometric supination contraction, and 3) resting passively in a supinated position while in the splint. EMG signals were pre-amplified, digitized at 500 Hz, and later analyzed on a computer. During the analysis, the raw data was rectified and peak activity was averaged for each of the three conditions.

A repeated measures ANOVA was utilized to determine statistical significance between the EMG measurement conditions. A post-hoc Tukey multiple comparison test was then utilized to further specify significant differences between the measurement conditions.

Results:

Range of Motion Results

Average PROM increased from the initial rehabilitation phase to middle phase and also from the middle to discharge phases of rehabilitation (Fig. 4). The greatest increase was from an initial average of 34.0^0 to an average of 71.8^0 at the middle phase of rehabilitation. PROM then increased from an average of 71.8^0 at the middle phase of rehabilitation to 82.3^0 at discharge. Significant differences in average PROM between subjects and between phases of rehabilitation ($p<0.001$) were noted. Post-hoc analysis revealed significant average PROM differences between initial and middle phases ($p<0.05$), but not between middle and discharge phases of rehabilitation.

Average AROM also increased from initial to middle and from middle to discharge phases of rehabilitation (Fig 4). The greatest increase was from an initial average of 27.0^0 to an average of 57.3^0 at the middle phase of rehabilitation. AROM then increased from an average of 57.3^0 at the middle phase of rehabilitation to 72.3^0 at discharge. ANOVA results demonstrated statistically significant differences in average AROM between subjects and between phases of rehabilitation ($p<0.001$). Post-hoc Tukey testing also revealed statistically significant average AROM differences between initial and middle phases and middle and discharge phases of rehabilitation ($p<0.05$).

Radiologic and Electromyographic Results

The X-ray film images (Fig 5) indicate that the radius and ulna alignment is nearly identical between active supination and the passive, resting supinated position in the dynamic supination splint regardless of elbow position. EMG results determined average supinator muscle activity as follows: 7.8mV (SE = .0004) at rest, 7.8 mV (SE = .0004) when splinted in

supination, and 68.0 mV (SE = .004) during a maximal isometric effort (Fig 6). Relative supinator muscle activity, when splinted in supination, was found to be 98.7% of the average resting value and 11.5% of the maximal effort EMG.

ANOVA results indicate a statistically significant difference between the three EMG measurement conditions ($p<0.001$). Post-hoc Tukey testing determined a statistically significant difference between the resting and splinted EMG values versus the maximal effort EMG value ($p<0.05$), but there was no significant difference between resting versus splinted EMG values.

Discussion:

The multiple patient cases indicate that AROM and PROM increased significantly from the beginning to the end of therapy. PROM increased to an average of 82.3^{0}, which falls within the normal range of 80^{0}-90^{0}.[1] AROM, however, did not fall within this range with an average of 72.3^{0}. This is not unexpected as the dynamic splint is a passive modality and AROM should improve with weaning from the splint and increased strengthening and functional use. We believe the increase in AROM is likely more a result of the other active treatments (AAROM, AROM, and resistive exercise) rather than the passive dynamic supination splint. The only change in ROM that was not statistically significant was the increase in PROM from middle to discharge phases of rehabilitation. This may indicate that the greatest benefit from the splint was obtained during the initial to middle phases of rehabilitation when large gains in ROM were possible.

It was not within the scope of this study to determine the benefits of the splint versus the other treatment techniques utilized in this study. The dynamic supination splint was applied when supination gains became recalcitrant to the other treatment techniques. After the splint was applied PROM increased significantly, as indicated by the largest PROM increase being from

initial to middle phases of rehabilitation. Therefore, the conclusion that the dynamic supination splint assisted significantly in increasing PROM can be made, at least as it applies to the subjects within this descriptive study.

The radiographic images demonstrate nearly identical alignment between the radius and ulna with active supination and resting in the splint both with the elbow flexed and extended. Although the wrist variance view may not provide the best view of radius and ulna alignment, it was chosen because it is a standardized position that reduces the effect of gravity in assisting passive supination. The positioning for the extended elbow radiograph is undescribed in the radiology literature and was chosen to provide evidence supporting the splint's ability to supinate the forearm with the elbow extended.

The EMG data clearly indicates that the splint is a passive modality. It was previously believed that the dynamic supination splint must have a proximal attachment, above the elbow, to generate an adequate passive supination force. "Adequate" is defined as a force significant enough to place the forearm in a supinated position. The combination of the radiographic images and the EMG data indicate that the splint does passively position the forearm in supination, despite the fact that the proximal margin does not cross the elbow.

These assessment approaches were used so as to couple the clinical outcomes with some information on the mechanical effectiveness of the splint. Heretofore, no studies exist that provide clinical outcome data utilizing dynamic supination splinting. Therefore, a comparison of outcomes versus alternative treatment/splinting techniques is not possible at this time. Nor is it possible to generalize the use of this splint with other patients beyond these described here. We do, however, feel that the retrospective increase in supination ROM, coupled with the radiographic images and EMG data make a compelling argument as to the merits of this splint.

Our clinical experience suggests that the less functionally inhibiting a splint, the more often the patient will wear the splint. Flowers and LaStayo[13], have reported that the longer a splint is worn, greater total end range time (TERT), the greater the return in PROM. As stated previously, all other dynamic supination splints cross the elbow, thus requiring the elbow to be fixed at 90^0 and inhibiting functional elbow motion while wearing the splint. This new supination splint does not cross the elbow, thereby allowing functional elbow flexion and extension. Since the splint is dynamic, the patient may also temporarily pronate the forearm as needed for function. We believe this dual ability to flex and extend the elbow and temporarily pronate the forearm increases the patient's functional use and thus, increases compliance and splint wearing time.

Other important factors in patient compliance are comfort and ease of donning/doffing. Subjectively, no subjects reported limiting their wearing time due to discomfort. All subjects also demonstrated the ability to don and doff the splint independently. This is important, as patients that live alone must be able to manage the splint with one hand.

Perhaps the greatest limitation of this study was that the TERT splint dosage was not specifically prescribed, as patients were instructed to wear the splint for 4-8 total hours per day. In the future, a prospective study utilizing a control group with no splinting and another group utilizing a splint that crosses the elbow would be beneficial for comparison of outcomes.

Description of Torque:

While the amount or source of torque production was not measured quantitatively, we speculate that the supination force is generated via the theratube that connects to points at both the distal ulnar wrist level and at the proximal radial forearm (Fig A-1 (D)). The theratube, when placed over the outrigger, lies over the rotational axis of the forearm. In doing so, the torque is

generated at the distal and proximal ends of the splint. The distal force creates a supination moment and the proximal force creates an equal and opposite pronation moment. In order to effectively create only the desired supination torque, the proximal force must be mitigated. Traditional forearm rotation splints place the proximal attachment above the elbow so that the humerus can effectively cancel the pronation moment. With the "corkscrew" design of this splint, the proximal torque is eliminated via the thermoplast that wraps posteriorly from the lateral forearm to near the medial epicondyle. As the strap from this posterior region to the volar thermoplast is secured, the undesirable force is negated. Thus, the only torque that remains is the supination force transmitted to the distal forearm.

It is important to note that the force applied via the theratube must be sufficient to create adequate torque to overcome the resistance not only generated by the soft tissues, but also the resistance inherent to the thermoplastic material itself. The force, and the subsequent torque, depend on the: 1) spring quality of the theratube selected, 2) length of theratube, 3) height of the outrigger, and 4) resistance/thickness of splinting material. Our control of these variables was mostly through empirical observation and not via quantitative experimental methods. For more information see the appendix.

Conclusion:

All dynamic supination splints to date require the elbow to be fixed at 90^0. With the elbow in this position, functional elbow motion is limited. This descriptive study indicates that this new dynamic supination splint, which does not cross the elbow (thereby allowing elbow flexion and extension), is clinically effective in increasing passive supination. EMG data and the radiographic images indicate that the splint does passively position the forearm in supination.

Therefore, the dynamic splint in this study is clinically and mechanically effective despite its position which allows flexion and extension of the elbow.

References:

1. Norkin CC, White DJ. Measurement of Joint Motion: A Guide to Goniometry. 2nd ed. Philadephia, PA: F.A. Davis, 1995.

2. Morrey BF, Askew LJ, An KN, Chao EY. A biomechanical study of normal functional elbow motion. J Bone Joint Surg-American Volume. 1981; 63(6):872-877.

3. Werner FW, An KN. Biomechanics of the elbow and forearm. Hand Clinics. 1994; 10(3):357-373.

4. Murphey MS. An adjustable splint for forearm supination. American Journal of Occupational Therapy. 1990; 44(10):936-939.

5. Kapandji IA. The upper limb as logistical support for the hand. In: Tubiana R (ed). The Hand. Philadelphia, PA: Saunders, 1981:94-106.

6. Morrey BF. The Elbow and its Disorders. 3rd ed. Philadelphia, PA: WB Saunders, 2000.

7. Bunnel S. Splint spring to supinate or pronate the hand. J Bone Joint Surg.. 1949; 31A:664.

8. Ballinger PW. Merrill's Atlas of Radiographic Positions and Radiologic Procedures. 8th ed. St. Louis, MO: Mosby, 1995:83-85.

9. Schultz-Johnson K. Splinting the wrist: mobilization and protection. J Hand Ther. 1996; 9:165-177.

10. Jaffe R, Chidgey LK, LaStayo PC. The distal radioulnar joint: anatomy and management of disorders. J Hand Ther. 1996; 9:129-138.

11. Laseter GF, Carter PR. Management of distal radius fractures. J Hand Ther. 1996; 9:114-128.

12. Colello-Abraham K. Dynamic pronation-supination splint. In: Hunter JM, Schneider LH, Mackin EJ, Callahan AD (eds). Rehabilitation of the Hand: Surgery and Therapy. 3rd ed. St. Louis, MO: Mosby, 1990:1134-1139.

13. Flowers KR, LaStayo P. Effect of total end range time on improving passive range of motion. J Hand Ther. 1994; 7:150-157.

Table 1. Diagnoses

Subject	Diagnosis	Fixation
1	Distal Radius Fracture	ORIF
2	Distal Radius and Ulna Fracture with Ulnar Osteotomy	
3	Distal Radius Fracture	Cast
4	Distal Radius Fracture	External Fixator
5	Distal Radius Fracture	External Fixator
6	Distal Radius Fracture and Osteotomy	ORIF
7	Radial Head Fracture/Excision	Cast
8	Proximal Ulna and Trochlea Fracture	ORIF
9	Radial Head Fracture/Excision	None
10	Distal Radius Fracture	Cast
11	Distal Radius Fracture	ORIF

Table 2. Demographics

<u>Sex:</u> Male Female	 2 subjects (18%) 9 subjects (82%)
<u>Age:</u> Range Average	 38-70 years 48.3 years
<u>Hand Dominance:</u> Right Left	 11 subjects (100%) 0 subjects (0%)
<u>Involved Hand:</u> Right Left	 6 subjects (55%) 5 subjects (45%)

Table 3. Visits

<u>Total Number of Visits:</u> Range Average	5-26 visits 17.7 visits
<u>Number of Visits before splint:</u> Range Average	1-13 visits 5.0 visits

Table 4. Passive Range of Motion (Degrees)

Subject	Visit Number																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	15	18	19	20	23	25	26
1	0	+		50						80*										90
2	+				70		70						80*						80	
3	50	+		80*					90											
4	55+	90*			90															
5	60			+			75*				80				80					
6	55+	80*	80																	
7	40		+					80*					90							
8	0												+	60*		65	65			
9	20						+		50			60*				70		80		
10	0				10	20				+		40	50*		60					80
11	40				+	45	50	55*		60		70		75	80					

Table 4. Passive Range of Motion (Degrees)

Blank spaces indicate that no ROM measurements were obtained on that date. Due to the retrospective nature of this review, measurements were not obtained at regular intervals other than on the initial and final visit.

* Indicates measurement used for middle phase of rehabilitation, which was determined as the closest visit on which a ROM measurement was made to the total number of visits divided by two

\+ Indicates visit when splint was applied, which was determined by inadequate ROM gains or per physician referral.

Table 5. Active Range of Motion (Degrees)

Subject	Visit Number																		
	1	2	3	4	5	7	8	9	10	11	12	13	15	18	19	20	23	25	26
1	0	+							70*										80
2	+				50	50						50*						70	
3	50	+	70*					90											
4	50+	70*			80														
5	50			+		70*				70				80					
6	50+	60*	70																
7	40		+				60*					70							
8	0											+	45*		50	55			
9	30					+					50*						80		
10	0								+			40*							50
11	0				+		45*						60	70					

Table 5. Active Range of Motion (Degrees)

Blank spaces indicate that no ROM measurements were obtained on that date. Due to the retrospective nature of this review, measurements were not obtained at regular intervals other than on the initial and final visit.

* Indicates measurement used for middle phase of rehabilitation, which was determined as the closest visit on which a ROM measurement was made to the total number of visits divided by two

+ Indicates visit when splint was applied, which was determined by inadequate ROM gains or per physician referral.

Figure 1. Rolyan® Preformed Dynamic Pronation/Supination Splint. Photograph supplied courtesy of Smith & Nephew Rehabilitation. Note how the proximal component of the splint fixes the elbow at approximately a 90^0 flexed position.

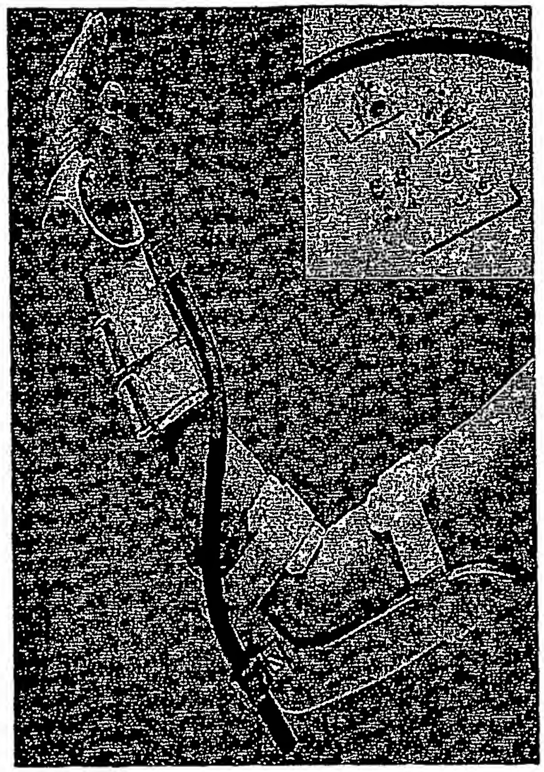


Figure 2. Radiographic positioning. Subject is positioned with arm abducted to 90^0 and elbow flexed at 90^0 (the standard variance position). Three forearm rotation conditions were filmed utilizing the wrist variance position. A fourth radiograph was taken with the elbow fully extended and the humerus internally rotated. Here she is shown maximally positioning the forearm in supination. Films were also taken, not shown here, in the neutral position, in a passive supinated position while wearing the splint with elbow bent, and passive supinated position while wearing the splint with elbow extended.

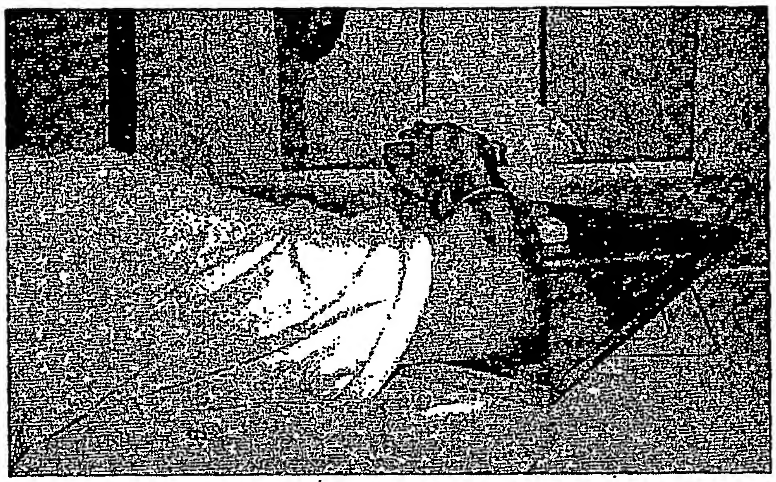


Figure 3. EMG Positioning. Electrodes were placed over the supinator and bicep with a common ground over the ipsilateral scapula. EMG analysis was used to study three conditions: 1) resting, quiescent muscle position, 2) maximal isometric supination contraction, and 3) resting passively in a supinated position while in the splint.

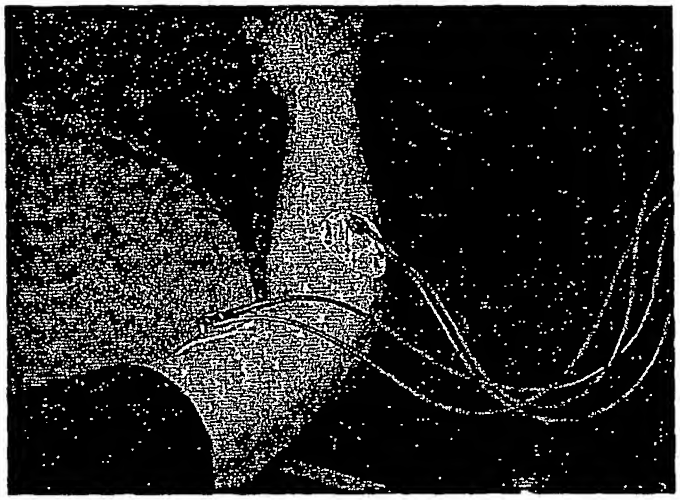


Figure 4.

Effect of Splint on Supination

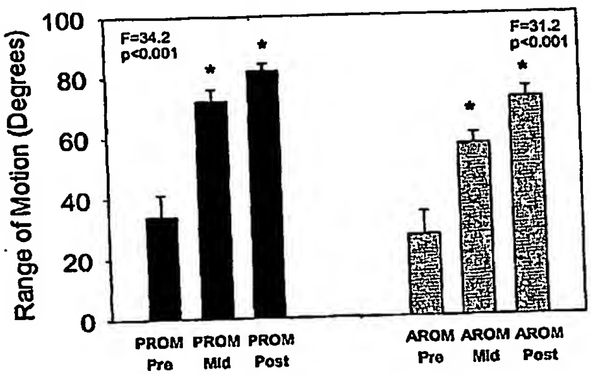


Figure 4. ROM Results. The effect of the supination splint on both supination PROM (black bars) and AROM (grey bars). Measurements were made: 1) initial (pre-splint) phase, 2) middle phase of rehabilitation, and 3) discharge (D/C) phase. For both PROM and AROM the middle and D/C supination range of motion measures were significantly (* = $p<0.05$) greater than the initial (pre-splint) measurement. Error bars = 1 SEM.

Figure 5. Radiographs. (A) Forearm at rest, (B) Maximal forearm supination, (C) Passive position of forearm with dynamic supination splint and bent elbow, (D) Passive position of forearm with dynamic supination splint and straight elbow. Note that position (B), (C), and (D) look nearly identical in terms of the supinated position of the radius relative to the ulna.

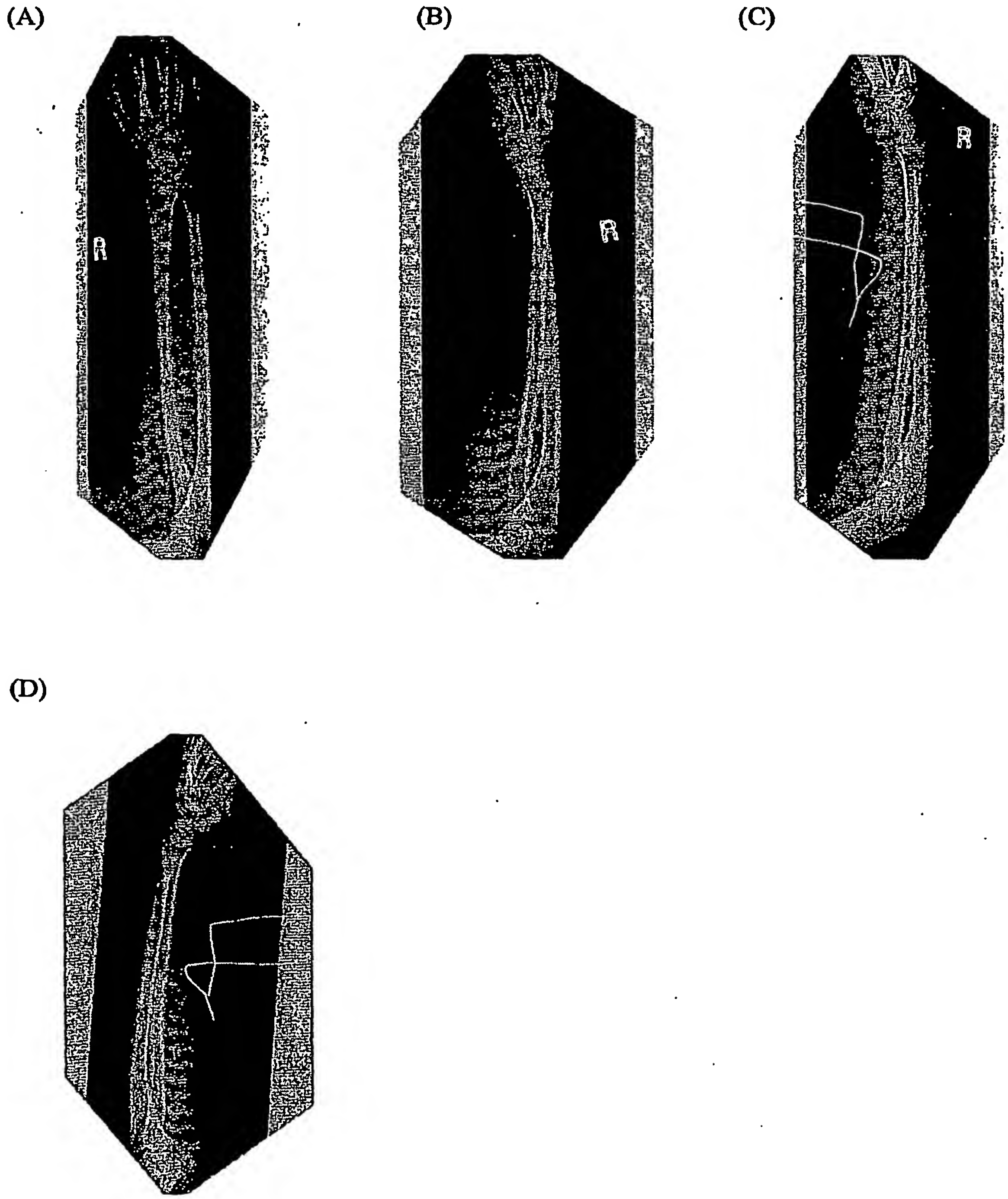


Figure 6.

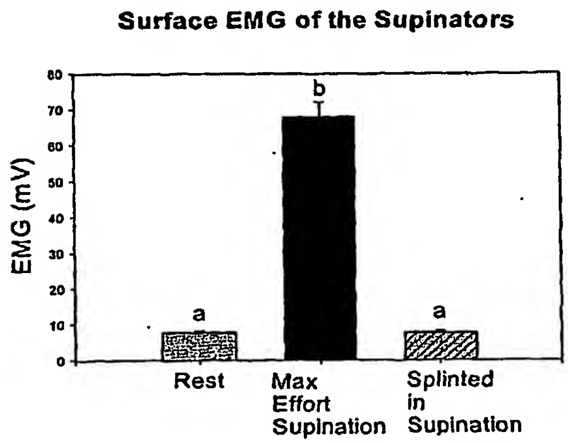


Figure 6. EMG Results. The repeated measures ANOVA: F=216.58 and the p value <0.001. The Tukey post hoc multiple comparison test found significance between the conditions marked by differing letters, while similar letters indicate no significant difference. Note that the passive supinated splinting EMG is essentially identical to the passive resting position. Error bars= 1 SEM.

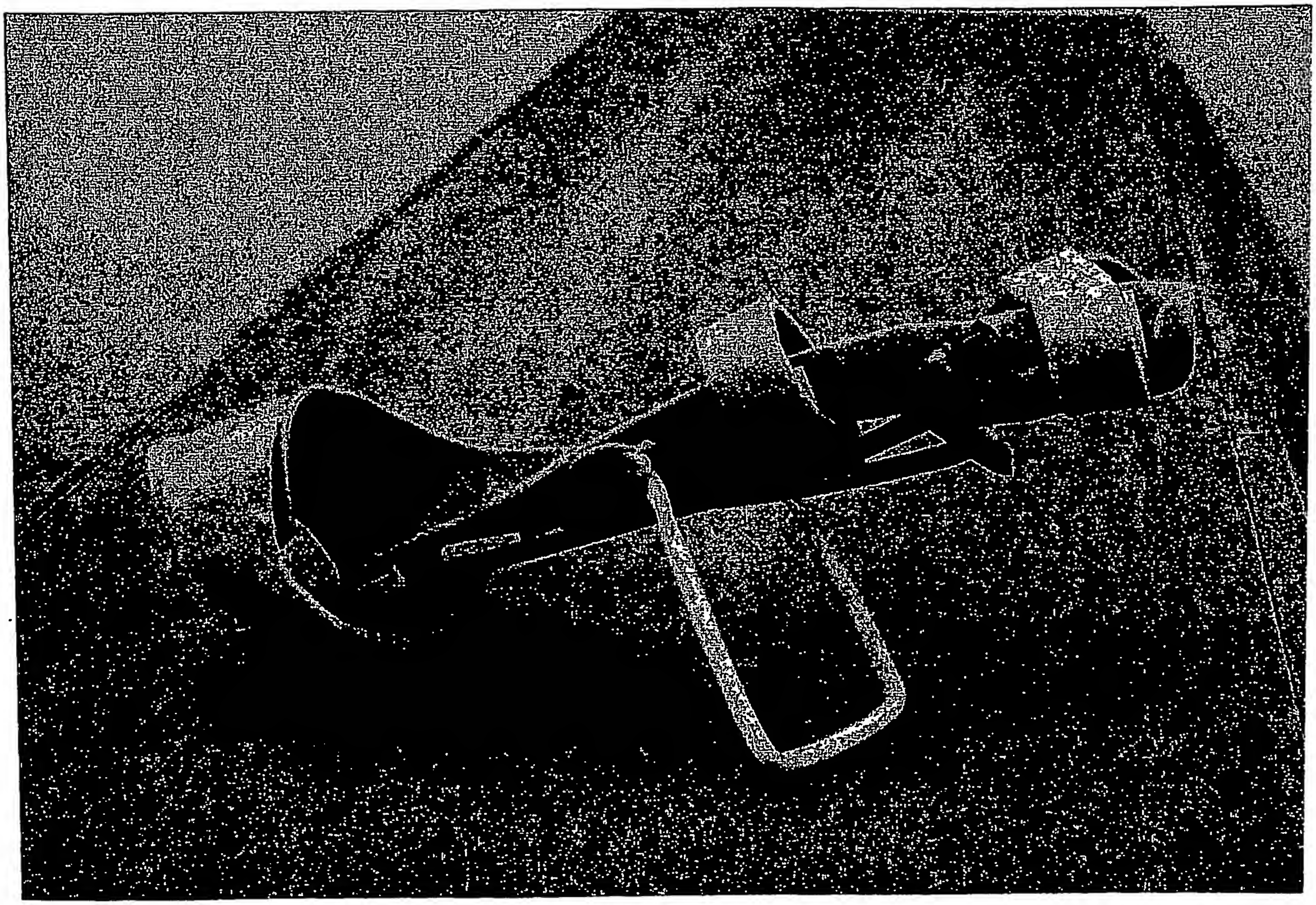


FIG. 7

FIG. 8

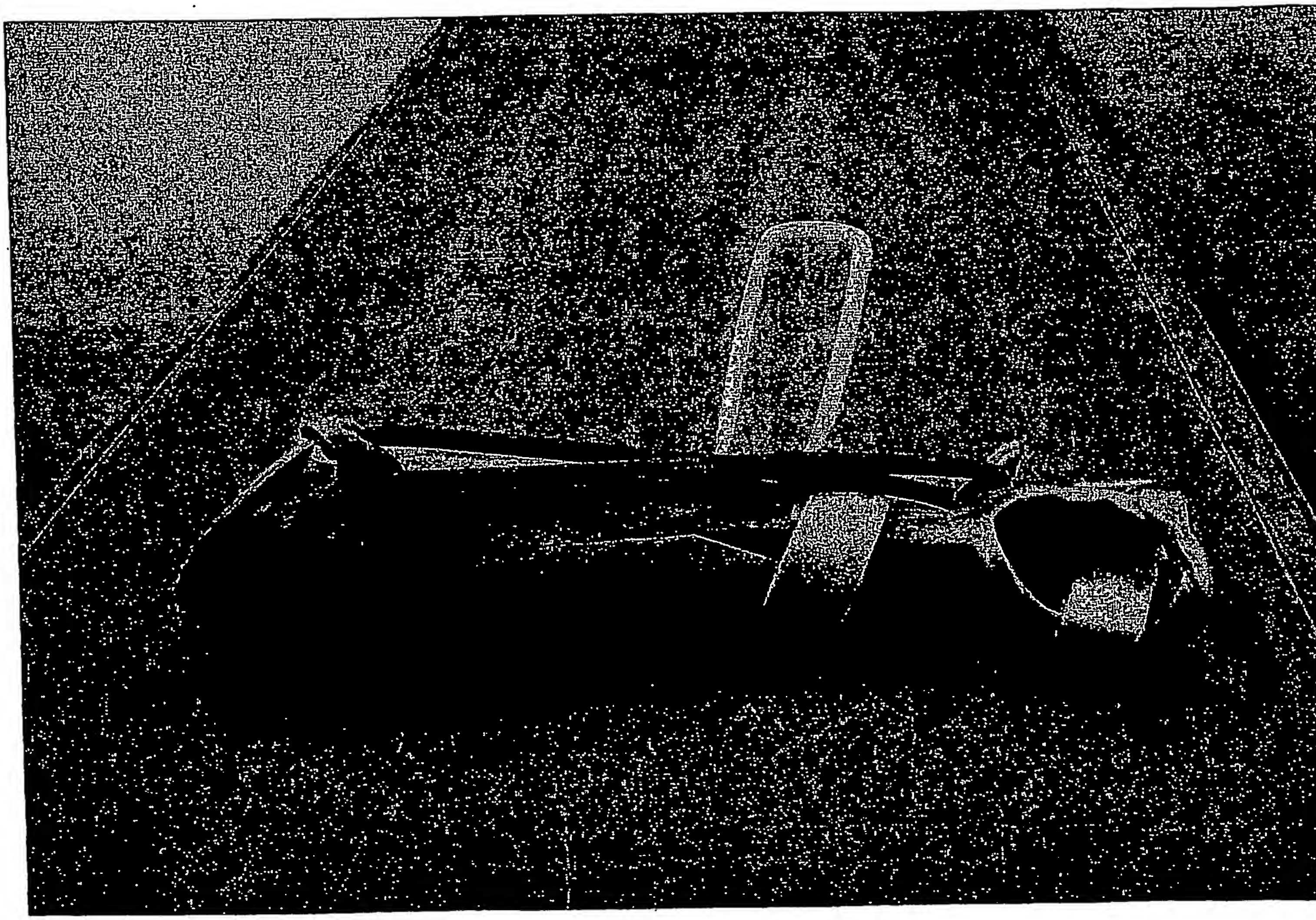


FIG. 9

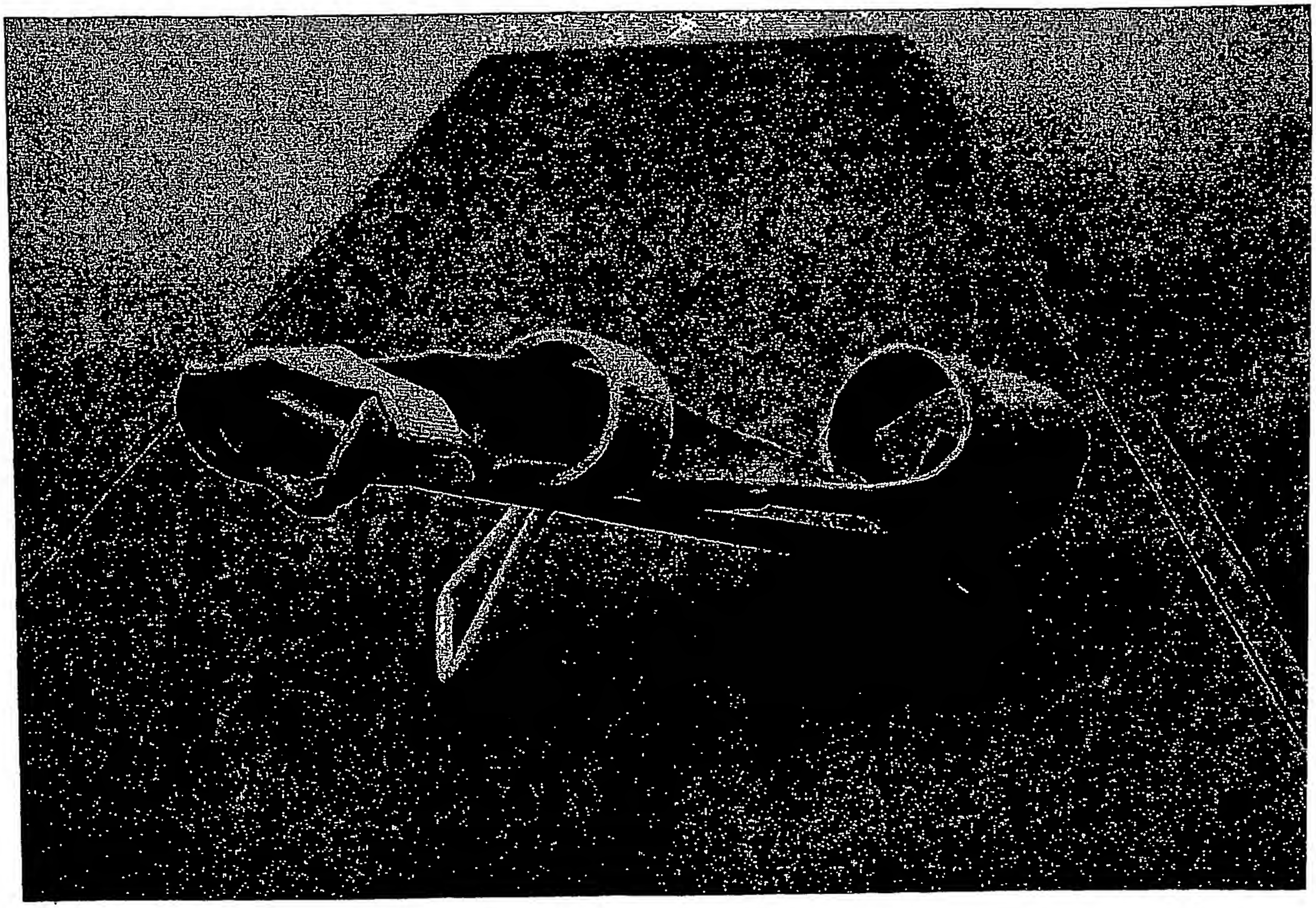


FIG. 10

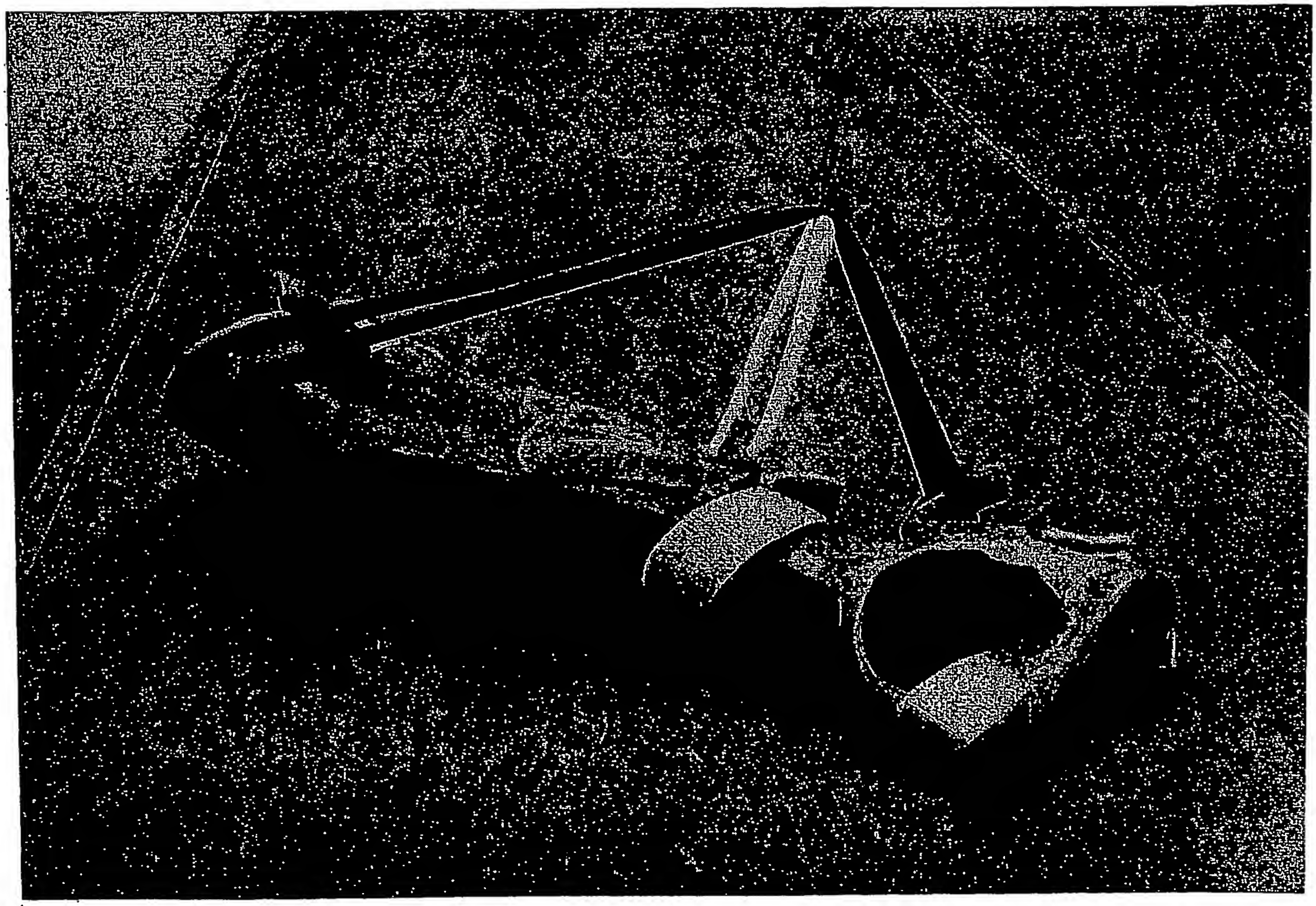


FIG. 11

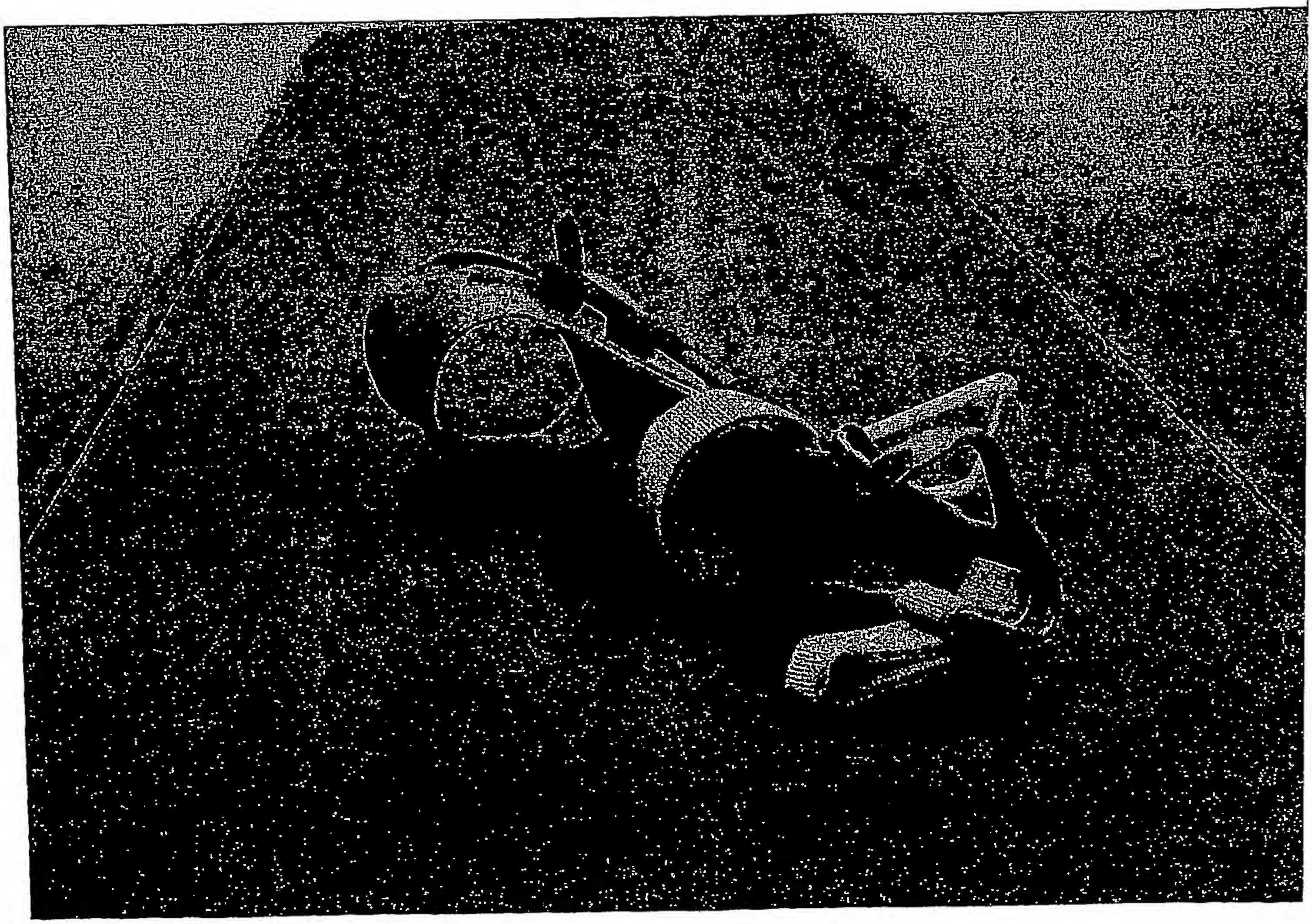


FIG. 12

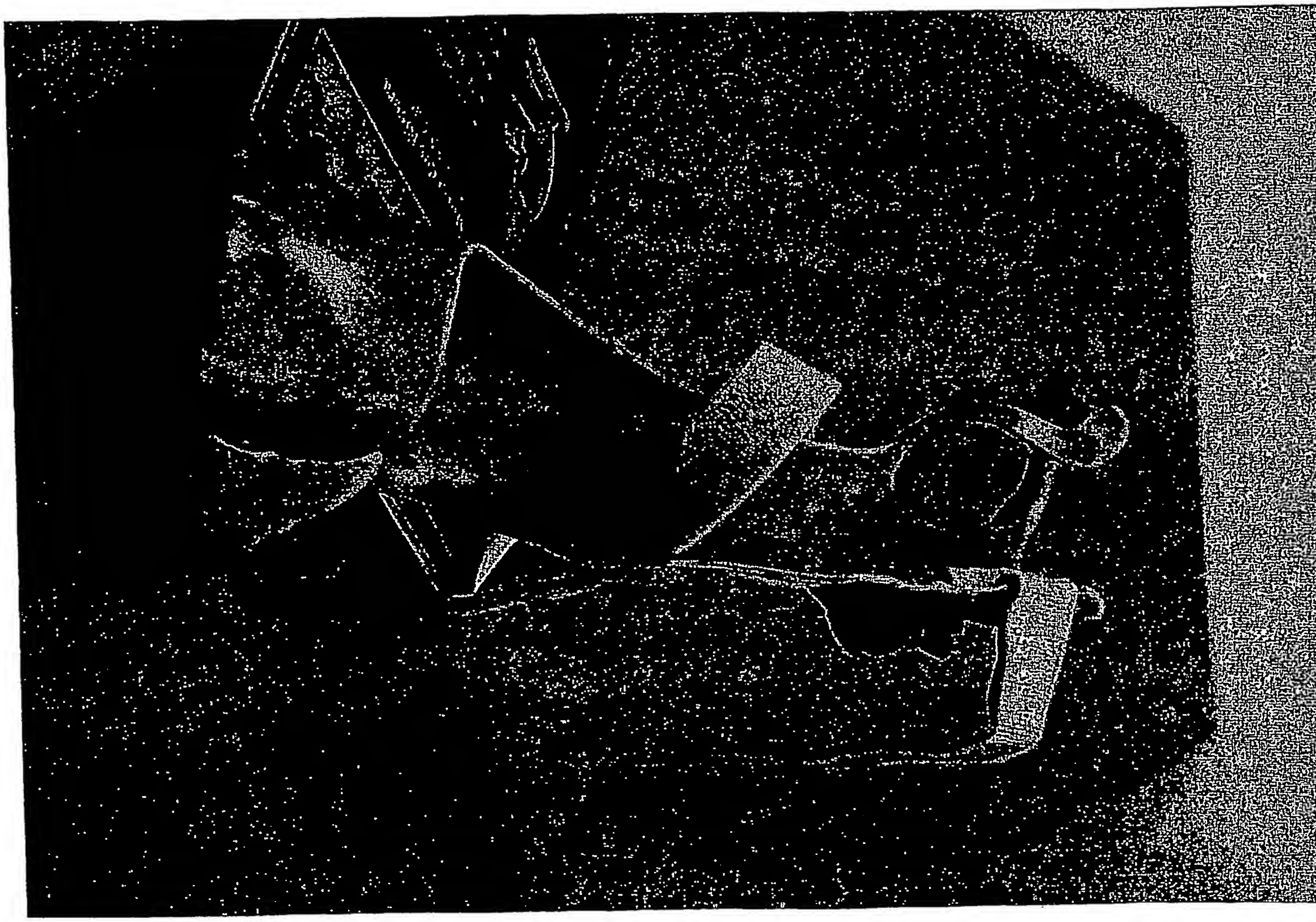


FIG. 13

Appendix

Splint Design and Fitting:

The basic premise of the splint is a "corkscrew" about the axis of forearm rotation which biases the forearm toward a supinated position. The splint pattern begins with what resembles a forearm based neutral wrist splint. Progressing proximally from the wrist, at approximately one-third of the radius length, the pattern arcs laterally around the radius. The splint progresses circumferentially around the forearm, ending slightly medial and distal to the medial epicondyle. A picture of the template can be seen in figure A-1. As with any template design, varying forearm length and girth must be taken into consideration.

When fitting the dynamic supination splint, it is recommended that you place the patient in supine with the shoulder flexed to approximately 45^0 and the elbow extended. The splint is placed volarly, as in fitting a basic neutral wrist splint. Caution must be taken to ensure that the wrist is secure and stable in the splint. Adequate room must be provided to allow thumb CMC mobility and full metacarpal phalangeal joint flexion. With the distal aspect of the splint secure, begin wrapping the material radially and dorsally. The radial side of the splint must extend to just distal to the lateral epicondyle, at the area of the radial head. The splint then continues to wrap circumferentially around the forearm, concluding slightly distal and medial to the medial epicondyle. Care should be taken to properly flare the proximal volar aspect of the splint, to allow elbow flexion to 90^0 without pinching in the antecubital fossa.

An outrigger is constructed and placed at approximately mid-radius at an angle so that it transects the long axis of the forearm, which is approximately a line from the radial head to the ulnar styloid. The outrigger should be five inches in height and three inches wide. These measurements were obtained via trial and error experimentation as five inches in height provides

adequate torque and three in width provides an adequate base of support. The outrigger is secured to the splint with aquaplast. Two hooks are then fastened to the splint for attachment of theratube to provide the dynamic force along the axis of forearm rotation. The hooks are made out of 3-inch by 2-inch pieces of aquaplast. The aquaplast is heated and folded lengthwise, then molded into a "V" along its length. The hooks are placed at the level of the ulnocarpal joint distally and the radial head proximally. The hooks should be positioned along an imaginary line corresponding to the axis of forearm rotation. For this reason, it is recommended to place the outrigger and hooks on the splint while the patient is wearing it.

A securing strap is placed dorsally at the metacarpals to secure the wrist and hand. Another strap is placed mid-forearm to secure the forearm in position. Finally, a strap is placed proximally that runs from the ulnar end of the splint to the lateral/radial side of the forearm. Theratube is then tied, as to form a loop, with each end attached to a hook. Once the ends are secure, the theratube is lifted over the top of the outrigger to provide the dynamic tension.

Splinting Materials:

The splint is constructed with 1/8-inch aquaplast. The same material is used to form the hooks and secure the outrigger in place. The outrigger is constructed from 1/8-inch aquatube with 1/16-inch copper wire inside. One inch strapping material is used distally and 2-inch straps are used at the mid-forearm and proximal levels. Theratube length is variable depending upon length of each patients forearm. However, there should be no slack in the theratube after it has been attached to the hooks. Theratube tension is also variable, depending on patient tolerance and degree of stiffness. We (MJL, AEV) recommend using the lowest tension at which the patient feels a "pull" and resistance to pronation. While the dosage of over-pressure into supination can vary some, the critical component of the splint wearing prescription is thought to

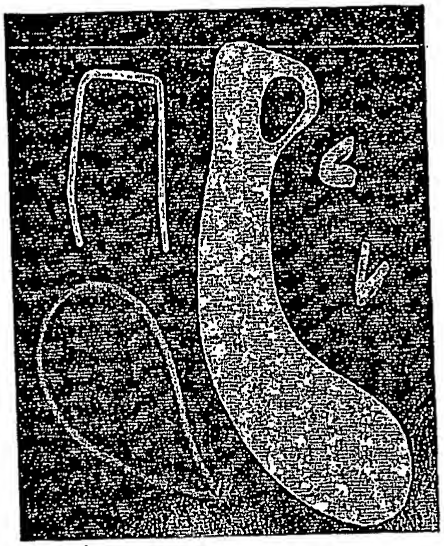
be the TERT. As Flowers and LaStayo[13] have demonstrated, it is not necessarily the tension, but the longer wearing time that influences changes in mobility.

Additional Information:

To assist in fabrication of the splint, a video is available for download at http://www.nau.edu/hp/lee-jht-splintvideo.

Figure A-1. Dynamic Supination Splint Fabrication. (A) Materials: Outrigger, theraband, hooks, and the main "corkscrew" piece. (B) Wrapping of material around forearm: Begin by wrapping the material radially and dorsally. The radial side of the splint must extend to just distal to the lateral epicondyle, at the area of the radial head. The splint then continues to wrap circumferentially around the forearm, concluding slightly distal and medial to the medial epicondyle. (C) Application of outrigger: The outrigger is constructed and placed at approximately mid-radius at an angle so that it transects the long axis of the forearm. The outrigger should be five inches in height and three inches wide. (D) Completed splint: Notice that the subject is able to fully extend the elbow and that the proximal margins do not cross the elbow thus allowing flexion and extension.

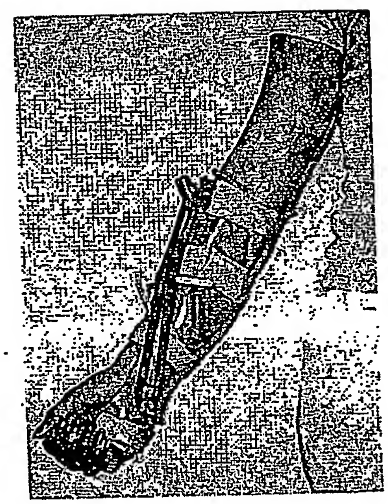
(A)



(B)

(C)

(D)



An exemplary splint provided in accordance to aspects of the present invention are also shown in FIGs. 7-13. It is understood that the particular size, materials used, placement of the Velcro, the anchors for the Thera-Band band, and the curvature and contour of the splint are exemplary only and that other sizes, configurations, and materials used may be incorporated

without deviating from the scope of the present invention. For example, high temperature resistant thermoplastics such as KRATON® from Shell Chemical, polypropylene-polyethylene, PVC, and other similar materials may be used without deviating from the scope of the present invention.

Incorporation By Reference:

Applicants hereby incorporate herein by reference, any and all U.S. Patents, U.S. applications, and other documents and printed matter cited or referred to in this provisional application.

CLAIMS

What is claimed is:

1. A supination splint comprising a splint body having a first strap for fixing a first part of an arm and a second strap for fixing a second part of the arm; the splint body further comprising first anchor and a second anchor and a bridge disposed in between the first anchor and the second anchor, wherein a band is engaged to the first anchor and the second anchor and is in contact with the bridge to provide a torque to the splint body.

Abstract:

The purpose of this study was to: 1) Describe a dynamic supination splint that approaches the humeroulnar and humeroradial joints and is flared to allow flexion and extension of the elbow. 2) Provide retrospective data on effectiveness of this splint in patients with limited supination. 3) Provide radiographic and electromyographic (EMG) data that documents this splint's ability to provide a passive supination force. Eleven subjects treated for various elbow and/or wrist fractures leading to losses of forearm supination significantly increased their passive range of motion (PROM) from 34.0^0 at the initial visit to 82.3^0 at discharge and active range of motion (AROM) from 27.0^0 to 72.3^0. Radiographic images of the radius and ulna were identical in maximal voluntary supination and resting in the splint. Surface EMG was utilized to measure supinator muscle activity at rest, passively supinated while wearing the splint, and during a maximal isometric supination effort (without splint). Average supinator EMG activity was: 7.9mV at rest, 7.8mV in the splint, and 68.0 mV with maximal isometric contraction. Results indicate the supination splint is clinically effective in increasing supination PROM in these subjects. The EMG data and radiographic images indicate that the splint passively positions the forearm in supination even though the proximal margin of the splint does not cross the elbow.

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